

CENTER FOR BIOSECURITY, FOOD SAFETY, & PUBLIC HEALTH

> 6430 Stonehurst Circle . LakeWorth, Florida 33467

Phone 561-968-1575
Fax 561-968-3766
dfranco99@aol.com

President
Don A. Franco, DVM, MPH, DVPM

Administrator Ms. Dara John

Huntsville, Missouri 65259
Phone 660-277-3469
Fax 660-277-3466

2 5 0 4December 01/5/2200812:22

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD. 20852

Dear Sir or Madam:

This references the Food and Drug Administration (FDA) Docket No. 2002N-0273, proposed rule, Substances Prohibited From Use in Animal Food or Feed, published in the Federal Register, Vol. 70, No. 193, October 6, 2005, seeking comments.

The Center for Bio-security, Food Safety and Public Health (CBFSPH) is a registered corporation in the State of Florida with interest in the broad realm of feed/food safety related subjects. As such, the proposed rule is of interest to CBFSPH, and the Center offers its comments for consideration. In a brief thematic summary, CBFSPH supports the current 1997 feed rule, knows its value, is convinced that it works, and sees no need for additional rulemaking. Nonetheless, aspects/concepts of the proposed rule will be addressed to support CBFSPH's contention that no additional rulemaking is necessary.

References to tallow and mechanically separated beef (MSB) in the proposal will not be addressed, thus limiting the comments/discussion/ and recommendations of the proposed rule to the handling/processing of cattle carcasses and their parts, and specifically, the brains and spinal cords from cattle of any age not inspected and passed for human consumption and the entire carcasses of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed, and the impact on the rendering industry. There will also be no analogies to brains and spinal cords from cattle 30 months of age and older, since there is compelling scientific evidence to support that policy. Additionally, existing rules are in effect to address and mitigate any perceived current risks that could contribute to the transmission or amplification of infectious agents, presumably prions, that are linked to the transmissible spongiform encephalopathies (TSEs) of animals 30 months and older.

CURRENT ANIMAL FEED SAFEGUARDS/CONCEPTS OF RISK

02N-0273

C271

Prior to the diagnosis of BSE in the United States, FDA in 1997 instituted a final rule to prevent the "establishment and amplification" of BSE in the country through animal feed. That rule has worked well, was well supported by the rendering industry, and is affirmed by the degree of compliance of the rendering industry (the high 90 percentile) with the requirements of the rule. Based on objective analyses, and in consideration of the existing risks in the country today, FDA SHOULD NOT EXAMINE ANY FURTHER RULEMAKING OPTIONS. Additional rulemaking would be an absolute waste of resources and an unnecessary burden to both the regulating agency and the regulated industry. Regulations must address the current or potential risks, neither of which would contribute to the spread of BSE or the occurrence of variant Creutzfeldt-Jakob disease (v-CJD) in the country, which is associated with BSE and is non-existent in the U.S. The agency also has a moral obligation not to abuse its regulatory authority. There is a time for a rule, and it is not now!

Internal audits by the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) as early as 1993 established a model demonstrating the limited BSE risk that exists in the United States because of the policies instituted over the years, starting by necessary prohibitions and controls in 1989 to exclude the potentiality of live animals and their products entering the country from BSE infected countries. Additional policies and modifications followed on an as needed basis to strengthen the established firewalls by timely considerate actions based on the evolving epidemiology of the disease incidence in Europe, predominantly the United Kingdom. Realistically, the applied policies of the agency responsible for the control of BSE in the country (APHIS) were well constructed and worked well. It was a success story from any perspective. It even silenced the rabid critics that were predicting a "doomsday" incidence of BSE in the country and demanding additional regulations.

The "epicenter" of policy validation was the conclusion by epidemiologists of the Harvard Center for Risk Analysis (HCRA) at Harvard University and the Center for Computational Epidemiology at Tuskegee University, working under a USDA 1998 contractual agreement, that "the United States is highly resistant to any proliferation of BSE, and that measures taken by the U.S. government and industry make the United States robust against the spread of BSE." The aforementioned is a very compelling statement.

A further evaluation of the implications for BSE risk re-surfaced in the U.S. after case incidences in Canada in 2003, necessitating again another assessment of our vulnerability. HCRA was again summoned by USDA to reappraise the country's status. HCRA using hypothetical simulations

based on their initial epidemiological model came up with the same conclusions that they made initially i.e. that the U.S. presents a very low risk of establishing or spreading BSE SHOULD IT BE INTRODUCED! Be advised, the hypothetical model used to assess risk considered the factor of 10 infected animals, close to an absolute worst-case assumption based on the U.S.'s historical surveillance findings and status.

We have tested over half a million animals to date (closing in on 600,000), and the only positive animal was a 12-year old beef cow in June 2005. This BSE-positive animal was born and raised in Texas and under the existing regulatory regimen no part of the animal entered either the animal feed chain or human food. Interestingly, also, and the FDA is fully aware of the follow-up investigations, all exhaustive efforts for a causal association to feed was fruitless. A feed linkage could not be affirmed. Nonetheless, the agency went ahead with the prevailing assumption that "the BSE-positive cow most likely became infected before FDA's implementation of the 1997 ruminant feed final rule." While science is not averse to anecdotes, an agency should be totally transparent in this day and age and take opportunities to fully inform the public, including the obvious difficulties encountered in assessing information, and the frustrations in traceback, plus the fact that the conclusion of a feed inference was totally speculative, and an assumption.

It was highly unlikely that the "infected" animal had exposure to contaminated feed. The biology of prion diseases is complex and still awaits many unanswered questions. A point of epidemiological significance is that 67 cohorts of the "affected" herd exposed to the same husbandry and feeding conditions, all tested negative during the extended investigative surveillance. It is also not customary for ranchers in that part of the country to feed range beef herds with animal protein supplements. In essence, FDA must be conscious that Commission findings in the United Kingdom, exemplified by the Phillips Report speculated on other possibilities of BSE infectivity including the environment and genetics. The bottom line, nonetheless, is that under the current FDA rule, there was no risk to animal or human health, strongly verifying that the 1997 rule works, and has worked from its inception, since no part of the infected animal went into the feed/food cycle of production.

MEASURES TO ENHANCE FEED PROTECTION

The United States and Canadian feed regulations established in 1997 were logical at the time due to uncertainty, and the existing anxieties about risk, including the human health inferences linked to BSE and v-CJD in 1996. Additionally, the U.S. proactive controls were also implemented to assure our trading partners that the country was taking all

the needed precautions and safeguards based on the known epidemiological indicators accepted for assessing risk. In reality, we were addressing aspects/concepts of feed/food safety, public health and trade under one broad umbrella. These measures, even from the most pessimistic perspective, have worked to make the U.S. feed/food supply safe. The alleged v-CJD epidemic linked to BSE has now become an after-thought in medical communities, averaging 15 deaths a year globally and declining in incidence/prevalence. This changing profile has provided countries like the United Kingdom, the core focal point of infectivity, reason to start policies to fully trade freely in beef and beef products because of their claim that the established controls they instituted have worked. This will impact feed at a later date, albeit, in a guarded manner, with plans to start feeding animal proteins in the U.K. to other than cattle at a later date. And, that is not unreasonable. In actuality, the Department for Environment, Food and Rural Affairs (DEFRA) announced on November 7, 2005, effective immediately, "the rule which has stopped older cattle from entering the human food chain since March 1996 has been lifted and replaced with a BSE testing regime." The end of the Over Thirty Month (OTM) Rule follows acceptance by the Government in September of advice from the Food Standards Agency (FSA) that a robust testing regime has been developed. The move to replace the OTM policy by BSE testing, FSA advised the Ministers, is justified on the basis of the food-borne risk to consumers and proportionality in relation to the cost of maintaining the current rule. All of this from a country that had 90 clinical cases of BSE plus 253 cases through testing detected during the previous year, 2004, And, what are we doing in the United States where there is absolutely no basis for comparing risks? We are tightening rules!!!

If we are intent to use a European model as guidance in this country, the FDA would be advised to follow what the U.K. plans to do based on the current knowledge that the cries of Armageddon in 1996 and 1997 that BSE will kill millions were fallacious and that we collectively need to put BSE behind us. The current rule will do just that.

It is important to note that FDA, a public health agency, generated a "feed rule" in 1997, to preclude what was assumed to be a potential human health catastrophe with some activist groups, and non-traditional academics, predicting deaths in the thousands to millions. It was never realized, even in a country like the United Kingdom with 98 percent of all the reported cases and a population of about 58 million people, never exceeded 28 cases annually in the height of the v-CJD epidemic. To date this year, the global incidence of v-CJD is 3 cases. The feed rules worked in Europe and is currently working well in the U.S. No further inflation or additional rules are needed. It is ridiculous to promote any idea that the BSE agent is in the U.S. feed supply and additional feed protection

measures are necessary. That hypothesis heightened by the International Review Team (IRT) is typical of the European perception of risk, plus the subliminal lesson, do what we did to control the disease, regardless of your degree of risk. Learn from our experience. That is logical with reservations. Proposed regulations must reflect the existing conditions of risk and what is mandated to preclude the risks from introducing disease to cattle herds, and ultimately the protection of human health. To theorize that the BSE infectious agent is "embedded" in the feed cycle in this country defies the history and borders on irresponsible. That is not supported by any affirmative data.

A rule devoid of science for its supporting legitimacy does injustice to cattle producers, and the broad livestock "fraternity" that have worked collaboratively with feed ingredient and feed manufacturers and the responsible government agencies to heighten and encourage compliance. Everyone will pay a price needlessly. Indeed, we should be celebrating the success that we have experienced in this country instead of considering additional regulatory options that will disenfranchise every sector of the agricultural cycle of production—feed ingredient suppliers, feed manufacturers, livestock producers, slaughter/processing operations, and the residual perception that we have a problem that needs additional control measures. Our beef is safe and so is our feed!

THE SPECIFIED RISK MATERIAL (SRM) FACTOR

The proposal to limit risk material to brain and spinal cord is a sensible approach. It affirms infectivity found in clinical disease of BSE and is scientifically supportable and logical. In addressing the subject of "cattle not inspected and passed for human consumption" by a regulatory authority e.g. the Food Safety and Inspection Service or a State Inspection Program, and cattle that died on farms, regardless of age, the proposed rule reverts to surveillance data in the European Union as the exemplar to support its thinking (as proposed) that said material should be excluded from all animal feed. This type of thinking is contrary to the accepted science of BSE risk in this country.

The first discount is that the agency is using surveillance data from a sector of the world with 99.97 percent of all cases of BSE to format policies. While comparative data can be used, and should be used, to determine considerate and sensible regulatory options, there is enough surveillance information that has emerged in this country over the last 15 years (including all the risk assessments and special studies) that the agency should not be resorting to data from the absolute worst-case environment as comparatives or to validate their intent. We have also had a "feed rule" in place for about 8 years that could provide perspectives of

risk. This does injustice and mocks the basic tenet of relative risk. Realistically, risk if it is to be considered as a factor for assessment, must be contextual. Besides which, it has been universally accepted by people who have seriously studied the global governance of BSE, that policy-making in the United Kingdom, at least prior to March 1996 when v-CJD was initially defined as a new disease syndrome, was nothing but a series of catastrophic failures. In essence, there is no basis for a serious comparison to the U.S. that instituted a series of internal controls and established policies to preclude BSE from the onset of its diagnosis in 1986 in the U.K. The point is that the historical circumstances surrounding the initial diagnosis of BSE in the U.K. about two decades ago cannot be used as indicators or determinants for the U.S. today.

To add closure to the discussion of cause - effect of BSE in the U.K in contrast to the U.S., and compare the circumstances differentially, the historical record affirms in the U.S., MBM was fed to cattle for about 100 years without incident until the alleged June 2005, Texas 12-year old cow isolated incident. (This positive case is still in need of further analysis). Similar experiences existed in the U.K. until 1986 when several cumulative changes in rendering practices apparently contributed to the first reported case of BSE in that country. Interestingly, however, the theory that BSE resulted from changes in rendering methods has no validity. Rendering methods have never been capable of COMPLETELY inactivating TSEs (The Phillips Commission Report, 2001). It has also been accepted that we will never know for certain the origin of BSE in the U.K. that became a global challenge, but it is logical to conclude that the predisposing factors for the disease did not exist in the U.S. otherwise we should have had an outbreak based on the MBM feed history analogy vears ago.

Another discount of the proposal is to exclude brains and spinal cords from all cattle regardless of age. This is contrary to the characteristics of the disease. BSE has a clearly established age-related association. For example, it would be an absolute waste of resources to expect renderers to remove the brains and spinal cords from calves and obviously young animals (steers and heifers), or for that matter anything less than 30 months old. The agency speaks about the use of science in decisionmaking and then indulges in practices that do not conform to the accepted science. The inconsistency is disturbing and sends the wrong message to those who are willing to work with the agency objectively to obviate risks. Epidemiologically, based on the historical record of controls instituted as early as 1989, if the U.S. had never instituted a feed rule in 1997, we would still be experiencing the level of robustness that the country enjoys today. But, assuming the rule was good "window dressing" for trade and a semblance of comfort to cattle agriculture and feed manufacturers, the point is there is no need to go beyond what was

formatted in 1997, including some of the additional policies instituted on December 30, 2003 by two agencies of the Department of Agriculture (APHIS and FSIS).

REGULATORY PROPOSALS/IMPACT ANALYSIS

The suggested potential of spread of BSE to older cattle from "intentional or unintentional use of non-ruminant feed for ruminants or crosscontamination of ruminant feed with non-ruminant feed or ingredients" is a perfect example of how to divert from the relative-risk inferences experienced with the current rule in this country to worst-case projections and assumptions that are devoid of supporting data except more anecdotal "tales" linked to Europe. The precautions and changes made by the rendering industry at both great costs and refining of facilities, validated by compliance findings, demonstrate that after 8 years of the current rule, "mixing up" of feed and cross-contamination is not a problem. A point of interest reverts to the "so-called" positive Texas cow. The agency suggested that the likelihood was a feed association due to the cow's age and exposure to feed prior to the 1997 feed rule. Accepting that theory, why is it that no other cohorts from the "alleged" infected herd tested positive for the disease? The agency likely referenced the IRT report suggesting that "given the epidemiological evidence indicating that BSE agent was already circulating in ruminant feed prior to the feed ban in 1997." This was one of the most outrageous and irresponsible utterances ever made by a study team. Equally as irresponsible was the suggestion by the same team that cattle in the U.S. have been indigenously infected from Canadian and possibly European importations. This type of thinking we do not need in assessing risk in this country. There is no affirmation or validation for either of these statements, yet federal agencies hide behind these types of statements to promote an agenda. At best, it mocks the science of risk.

Carcass Disposal

Comments relating to disposal will intentionally not address the economic aspects of disposal costs, since more comprehensive and authoritative studies could provide that information. Problems about the environmental issues and the potential for non-disposal of material derived from cattle in general will be heightened to provide perspectives of risk that could impact BSE control initiatives negatively, even in a country with proven minimal risk of BSE transmission.

There are varying estimates of the amount of pounds of cattle material prohibited in animal feed (CMPAF) that have to be destined for some method (s) of disposal. Regardless of whose numbers are used, the impact

is real and involves millions of pounds of "potentially infectious" material that will have to be disposed of. Some of the disposal options, assuming that the proposed will be published in a final rule, are problematic and could contribute to more potential for dissemination of infectivity. The suggestion that landfills and composting could be considerate options for disposal defy the tenets of environmental health, especially with pathogens like prions that are characterized by the most resistant properties of known infectious agents. Even the attributes of incineration have flaws and contribute to atmospheric pollution. As a result, the agency (FDA) proposing the disposal options will not be administering segments of their own proposal options and should be conscious that what is done to the environment in one place will almost certainly affect it elsewhere. A systems approach is thereby needed to ensure that potential problems like carcass disposal are not examined in isolation, but in terms of how it interacts with and affects other segments of our environment and our daily lives.

There is research evidence that the infectious form of the prion is extremely resistant to degradation and that provides opportunities for environmental reservoirs of transmission. Using the scrapie agent as a prototype of potential prion transmission, Brown and Gajdusek (1991) showed that scrapie-infected fluid, mixed with soil, packed into perforated Petri dishes, and embedded within soil-containing pots, retained infectivity after a burial period of three years. The historical evidence also suggests that environmental decontamination of prions would be extremely difficult to accomplish. This is exemplified by the research experience of many working with scrapie facilities that recognize that premises remain infectious for long periods. The same applies to chronic wasting disease (CWD). Assuming that BSE, a prion disease, would parallel the properties of scrapie and CWD is totally reasonable. Thus, there is the need for FDA to re-think some of the negative implications of some of the proposed cattle disposal methods.

Additional Measures to all animal food and feed

It is impossible not to indulge in repetition and remind the agency not to indulge in theories devoid of scientific support. With all the existing precautions in place, including compliance with the feed rule requisites, plus the country's minimal risk status, to suggest that the feeding of meat and bone meal (MBM) to non-ruminant species like pigs and poultry would be a potential risk for disease transmission to cattle "staggers" the imagination. The agency again resorted by referencing the "European experience" with the high levels of BSE infectivity to the U.S. and further made specific reference to the United Kingdom, a country with 98 percent of all BSE cases reported globally. These types of analogies make

the agency appear disingenuous and not intent to truly debate the subject objectively and fairly. A risk inference to be truly applicable and useful must be contextual when considering regulatory options. Additionally, there is no reason to indulge in the repetitious use of the British experience to highlight policy options, including the "scare factor" of citing experimental research that demonstrates transmission of BSE with lower infectious doses than originally anticipated. That information would be good for the archives, but does very little good as an applicable regulatory consideration to the U.S.'s current BSE epidemiology. We have enough data in the country to determine a sensible regulatory direction without the continuous emotionalizing of the European experience, exemplified by the United Kingdom's BSE dilemma.

I also consider it fruitless to remind the agency, since their scientists are fully aware of the fact, that swine and poultry, based on extensive transmission findings and publications, are not susceptible to prion or prion-like diseases that are of current interest to this proposed rule. Again, the agency must be advised to keep the subject in perspective. We have firewalls in place that are working, and need no additional rules other than the current feed rule that is working well to preclude risk of either the possible transmission or amplification of the infectious agent of BSE.

SUMMARY

Nineteen years after the initial outbreak of BSE in the U.K., assurances can be provided that the U.S. feed/food supply is safe based on the adequacy of the preventive measures that have been implemented. The planned prevention strategies and the commitment of the responsible government agencies, the cattle industry and the feed/rendering/food industries to work collaboratively to prevent BSE, and by inference, v-CJD, the human health counterpart, serve as a premier example of the attributes of working unified to achieve success. While BSE is a complicated and enigmatic disease, and continued caution should prevail. the mere fact that the U.S. from the onset established a series of rigorous preventive measures to ascertain that the disease will never gain a foothold proved to be prudent. The 1997 feed rule is an example of sensible controls. It works and will continue to work to provide the needed protection without any further regulatory intervention. It is time to put BSE behind us and move forward to other challenges. A failure to do so does an injustice to the science of risk assessment.

Donald

Don A. Franco

President, CBFSPH